Interview Summary

The Examiner contacted Applicants' representative on 1/22/2010 to propose an amendment to the claims which if accepted, would place the application in condition for allowance. The proposal has been revised in view of a subsequent conversation with Applicants' representative and is as follows:

Cancel claims 1, 2, 13, 32, 84, 106, 107, and 110.

12. (Currently Amended) ~~The~~A peptide ~~according to claim 1, wherein said peptide is~~ selected from the group consisting of PALKT (SEQ ID NO: 6), PSNST (SEQ ID NO: 8), PPNTT (SEQ ID NO: 9), STPPNTT (SEQ ID NO: 17), APSNSTA (SEQ ID NO 15), and SPALKTV (SEQ ID NO: 16).

35. (Currently Amended) A peptide selected from the group consisting of PALKT (SEQ ID NO: 6), PSNST (SEQ ID NO: 8), PPNTT (SEQ ID NO: 9), STPPNTT (SEQ ID NO: 17), APSNSTA (SEQ ID NO 15), and SPALKTV (SEQ ID NO: 16)~~The peptide according to claim 1, wherein X1, X2, and X3 may be the same or different, and each represents an amino acid residue~~, and wherein the peptide is linked to a polycationic nucleic acid-binding component.

42. (previously presented) The peptide according to claim 35, wherein the peptide is linked to the polycationic nucleic acid-binding component via a spacer element.

51. (Currently Amended) A non-viral transfection mixture comprising:

(i) a lipid component,

(ii) a polycationic nucleic acid-binding component, and

(iii) a peptide with a length up to 30 amino acids comprising an amino acid sequence selected from the group consisting of PSNST (SEQ ID NO: 8), PPNTT (SEQ ID NO: 9), STPPNTT (SEQ ID NO: 17), APSNSTA (SEQ ID NO 15), and SPALKTV (SEQ ID NO: 16), or a peptide consisting of PALKT (SEQ ID NO: 6).~~a peptide comprising the amino acid sequence PXIX2X3T [SEQ.ID.NO.:1], wherein X1, X2, and X3 may be the same or different, and each represents an amino acid residue.~~

54. (Previously Presented) The mixture according to claim 51, wherein the lipid component comprises one or more lipids selected from the group consisting of cationic lipids, lipids having membrane destabilising properties, and lipids having fusogenic properties.

65. (Currently Amended) A non-viral transfection complex comprising:

(i) a nucleic acid,

(ii) a lipid component,

(iii) a polycationic nucleic acid-binding component, and

(iv) a peptide with a length up to 30 amino acids comprising an amino acid sequence selected from the group consisting of PSNST (SEQ ID NO: 8), PPNTT (SEQ ID NO: 9), STPPNTT (SEQ ID NO: 17), APSNSTA (SEQ ID NO 15), and SPALKTV (SEQ ID NO: 16), or

a peptide consisting of PALKT (SEQ ID NO: 6).~~a peptide comprising the amino acid sequence PXIX2X3T [SEQ.ID.NO.: 1], wherein X~, X2, and X3 may be the same or different, and each represents an amino acid residue.~~

76. (previously presented) A process for the production of a complex according to claim 65, which comprises admixing components (i), (ii), (iii) and (iv) in the following order: lipid component, peptide, polycationic nucleic acid binding component, and nucleic acid.

80. (Currently Amended) A non-viral transfection complex comprising:

(i) a nucleic acid,

(ii) a polycationic nucleic acid-binding component, and

(iii) a peptide with a length up to 30 amino acids comprising an amino acid sequence selected from the group consisting of PSNST (SEQ ID NO: 8), PPNTT (SEQ ID NO: 9), STPPNTT (SEQ ID NO: 17), APSNSTA (SEQ ID NO 15), and SPALKTV (SEQ ID NO: 16), or a peptide consisting of PALKT (SEQ ID NO: 6).~~a peptide comprising the amino acid sequence PX1X2X3T [SEQ.ID.NO.: 1] wherein XI, X2, and X3 may be the same or different, and each represents an amino acid residue~~.

97. (Currently Amended) A method of transfecting a cell with a nucleic acid, which method comprises contacting the cell *in vitro* or *in vivo* with the transfection complex according to claim 65 or claim 80~~, or a viral vector according to claim 84~~.

98. (Currently Amended) A ~~pharmaceutical~~ composition comprising the transfection complex according to claim 65 or claim 80 ~~or a viral vector according to claim 84~~, said composition being in admixture or conjunction with a pharmaceutically suitable carrier.

99. (Currently Amended) A method for expressing a gene~~the treatment or prophylaxis of a condition caused~~ in a human or in a non-human animal with~~by~~ a defect and/or a deficiency in a gene, which method comprises administering the transfection complex according to claim 65 or claim 80 ~~or viral vector according to claim 84~~ to the human or to the non-human animal.

100. (Currently Amended) A method for inducing an immune response in~~the therapeutic or prophylactic immunisation of~~ a human or ~~of~~ a non-human animal, which method comprises administering the transfection complex according to claim 65 or claim 80 ~~or the viral vector according to claim 84~~ to the human or to the non-human animal.

101. (Currently Amended) A method of inhibiting the expression of a gene~~anti-sense therapy~~, which ~~method~~ comprises administering the transfection complex according to claim 65 or claim 80 ~~or the viral vector according to claim 84~~ to a human or to a non-human animal.

105. (Currently Amended) A kit comprising:

(i) a nucleic acid,

(ii) a polycationic nucleic acid-binding component, and

(iii) a peptide with a length up to 30 amino acids comprising an amino acid sequence selected from the group consisting of PSNST (SEQ ID NO: 8), PPNTT (SEQ ID NO: 9), STPPNTT (SEQ ID NO: 17), APSNSTA (SEQ ID NO 15), and SPALKTV (SEQ ID NO: 16), or a peptide consisting of PALKT (SEQ ID NO: 6).~~a peptide comprising the amino acid sequence PX1X2X3T [SEQ.ID.NO.:I],wherein X1, X2, and X3 may be the same or different, and each represents an amino acid residue, and, optionally~~,

(iv) a lipid component.

111. (Previously Presented) The peptide according to claim 12, wherein the peptide consists of the amino acid sequence APSNSTA (SEQ ID NO: 15).

The following issues were discussed by the Examiner and Applicant's representative:

- The Examiner identified prior art teaching peptides comprising the amino acid sequence $PX^1X^2X^3T$ (SEQ ID NO: 1) wherein X^1 is S, A or P, X^2 is N or L and X^3 is S, K, T or A, wherein said peptide has an A or V at the C-terminus and/or A, S, or T at the N-terminus and which are comprised of 7 to 30 amino acid residues, which reads on claims 1, 2, 13 and 32. As result, unity of invention is lacking *a posteriori* and the application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1: Group I, claim(s) 1, 2, 12, 13, 32, 110 and 111, drawn to a peptide comprising SEQ ID NO: 1; Group II, claim(s) 35, 51, 54, 65, 76, 80, 98 and 105 drawn to a peptide comprising SEQ ID NO: 1 wherein the peptide is linked to a polycationic nucleic acid-binding component and non-viral transfection mixtures; Group III, claim(s) 84, drawn to a viral vector

encoding SEQ ID NO: 1; Group IV, claim(s) 97 and 99-101, drawn to a method of transfecting a cell and a method of treatment or prophylaxis of a condition comprising administering a transfection complex; Group V, claim(s) 106, drawn to a bispecific antibody capable of binding to a virus and to a peptide comprising SEQ ID NO: 1; and Group VI, claim(s) 107, drawn to a fusion protein comprising a peptide comprising SEQ ID NO: 1 and an antibody capable of binding to a virus.

- The Examiner indicated that peptides consisting of SEQ ID NOs: 6, 8, 9, 15, 16 and 17 are novel and unobvious over the prior art and are enabled for use in non-viral transfection mixtures.
- The Examiner proposed, in order to expedite prosecution, to the limit the scope of the claims to peptides consisting of SEQ ID NOs: 6, 8, 9, 15, 16 and 17, and to restrict examination to claims drawn to peptides, non-viral transfection mixtures, and the methods of making and using said non-viral transfection mixtures, canceling claims 84, 106, 107, and 110.
- The Examiner proposed in order to avoid a rejection for lack of enablement to amend claims 98-101 as presented above.
- The Examiner requested that Applicant file a new IDS wherein the titles of all NPL documents are included, and amend the specification to comply with the sequence rules.
- Applicants' representative countered the original proposal with a request to include "open" or "comprising" language in claim 12. The Examiner stated that peptides comprising SEQ ID NOs: 6, 8, 9, 15, 16 and 17 are known in the art and that only peptides consisting of SEQ ID NOs: 6, 8, 9, 15, 16 and 17 are allowable. The Examiner agreed to consider open language in the claims drawn to transfection mixtures and modified the proposed amended

accordingly. The new proposal allows for open language for SEQ ID NOs: 8, 9, 15, 16 and 17 with an upper limit of peptide length of 30 amino acids as in original claim 32 and p. 19 of the specification and for closed language for SEQ ID NO: 6.

- The Examiner agreed to supply, by facsimile, references being considered with respect to the allowability of SEQ ID NOs: 6, 8, 9, 15, 16 and 17. These references include:

Hallbrink et al. (US 2008/0234183) teach cell-penetrating peptides comprising instant SEQ ID NO: 6 (claim 26 and SEQ ID NOs: 3389-3392) and the use of cell-penetrating peptides in non-viral transfection mixtures (paragraphs 0141-0147 and Example 9). Hallbrink et al. do not teach or suggest a peptide consisting of SEQ ID NO: 6 and provide no motivation to make such a truncation.

Punnonen et al (US 2005/0260605) teach a method for the use of phage display to select for polypeptides that can enter dendritic cells by, for example, receptor-mediated endocytosis (Example 3) and suggests the use of the polypeptides with a genetic vaccine (paragraph 0006). Punnonen et al. do not teach or suggest instant SEQ ID NOs: 6, 8, 9 or 15-17. Punnonen et al. do not teach screening of a library that necessarily contains SEQ ID NOs: 6, 8, 9 or 15-17.

Galbraith et al. (WO 01/12816) teach antigenic fragments of the porcine endogenous retrovirus (poERV) GAG polypeptide including TSLRPDITQPPSNSTT, which comprises instant SEQ ID NO: 8 (p. 17, peptide D). Galbraith et al. do not teach or suggest a peptide consisting of SEQ ID NO: 8 and provide no motivation to make such a truncation. Galbraith et al. do not teach or suggest using the GAG fragments in non-viral transfection mixtures.

Rose et al. (WO9704105) teach antigenic fragments of DNA polymerase of gamma herpes viruses including TDPALKT, which comprises instant SEQ ID NO: 6 (see p. 45, SEQ ID

NO: 103). Rose et al. do not teach or suggest a peptide consisting of SEQ ID NO: 6 and provide no motivation to make such a truncation. Rose et al. do not teach or suggest using the antigenic peptide in non-viral transfection mixtures.

Velicer et al. (US 5,976,787) teach a peptide of the HSV1 gene US2 polypeptide comprising SEQ ID NO: 9 at positions 82-86 (SEQ ID NO: 14). Velicer et al. do not teach or suggest a peptide consisting of SEQ ID NO: 9 and provide no motivation to make such a truncation. Velicer et al. do not teach or suggest using the antigenic peptide in non-viral transfection mixtures.